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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,642	08/04/2003	William Suttle Peters	13634.4003	7193

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EXAMINER

ALTER, ALYSSA M

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 10/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary	Application No. 10/634,642	Applicant(s) PETERS ET AL.	
	Examiner Alyssa M. Alter	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/20/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on August 15, 2005 (paper No. 3) has been received and considered. By this amendment, claims 1-2 and 19-23 have been amended, claim 18 has been canceled, claims 28-29 have been added and claims 1-17 and 19-29 are now pending in the application.

Response to Arguments

Applicant's arguments, filed on August 15, 2005, with respect to claims 1-17 and 19-29 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Lederman (US 6,210,318).

The Applicant correctly states that Lederman does not teach a physical connection between the stent (shell) and the balloon. Since the claims have been amended to include this limitation, the examiner finds the arguments persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-20, 23-26 and 28-29 are rejected under 35 U.S.C. 103(a) as being obvious over Lederman (US 6,210,318). Lederman discloses the claimed invention

except for the balloon or chamber attached to the shell. However, Lederman does disclose a stented balloon pump system and method, which employs "a pumping balloon subsequently deployed within the stent such that the stent is interposed between the pumping balloon and the body passageway within which the pumping balloon is operatively positioned, as seen in figure 1. However, the intent, to have a balloon operate within the confines of the stent disposed against the inner wall of an arterial vessel, remains that same. In addition, it is widely accepted to integrate working parts in the same functional environment. It would have been obvious to one having ordinary skill in the art at the time the invention was made to attach the balloon to the shell, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (see MPEP 2144.04)

As to claims 4-8 and 24-25, "expansion of the stent is often effected by inflation of an angioplasty balloon or the like within the stent, to force radial expansion of the stent until it contacts and/or adheres to the wall of the body passageway. In one embodiment of the present invention, pumping balloon 106 may be inflated within radially contracted stent 104, expanding stent 104 until it contacts the inner wall of descending aorta 152 and embeds itself therein. In an alternative embodiment, another balloon may be used for this purpose. If desired, the above noted stented aortic graft systems can be used, wherein the stent provides a scaffold-like support which can be expanded by outward radial pressure provided by a balloon or by virtue of self-expanding shape-memory materials such as nickel titanium alloy formulated to

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transform from martensitic to austenitic phase at body temperature, following delivery by catheter to the desired site" (col 8-9, lines 67 and 1-16).

As to claims 9-12 and 15, Lederman discloses, in col. 8, lines 18-56, numerous vascular and intra-aortic stents. Such examples of stent embodiments are: reinforcing stent constructed from a single elongated wire, stent formed of half-round wire, collagen-coated stent, cylindrical, open-ended intra coronary stent, radially-expandable stent, balloon-expandable, crush-resistance locking stent, compressive stent, intravascular radiallyexpandable stent, expandable intraluminal graft, expandable polymeric stent, self-expanding prosthesis stent and a stent with a thin graft material covering or lining, such as thinly woven polyester yarns shaped into tubular coverings to form aortic stented grafts of the type commercially available.

As to claims 13-14, figures 2A-2B and 3A-3B reveal the stent with the balloon extended around the full circumference of the stent frame. Since the balloon extends around the entire circumference of the stent lumen, the examiner considers balloon to extend around a part of the circumference of the stent lumen.

As to claims 16-17, figures 2A-2B displays "hole(s) 204 and 208 may be dimensioned to effectuate inflation and deflation of a desired rapidity. Any appropriate fluid or gas may be used to inflate and deflate pumping balloon 14 and balloon valve 15. In a preferred embodiment, however, a low molecular weight gas such as argon is utilized"(col. 7, lines 30-33). The examiner considers the Control drive mechanism 112 to be a fluid pressure source since it controls the pressure inside the pumping balloon.

As to claim 17, It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

As to claims 18-20 and 26, since the "balloon pump 102 is attached to a multi-lumen catheter 110, which is brought outside the body through the arterial tree, such as the subclavian artery 158, as shown in FIG. 1"(col. 5, lines 29-32), there is inherently an aperture in the artery to facilitate the catheter being "brought outside the body". In addition, the subclavian artery is located in the thorax and therefore is connected thoracoscopically.

2. Claims 21, 22 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lederman (US 6,210,318) in view of Kiyota et al. (US 5,453,076). Lederman discloses the claimed invention except for the sternotomy. Kiyota et al. teaches in column 12, lines 11-14, that it is known to surgically insert and arrange an internal cardiac assist apparatus between the sternum and the pericardium. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the placement of the cardiac support system as taught by Lederman since such a modification would alter the surgical procedure to meet specific patient needs.

As to claim 22, since "the shape-memory materials can be alloyed for later removal by intraluminal catheter flush with cooled saline to induce reversion to a reduced profile at martensitic phase for ease of withdrawal"(col. 9, lines 16-19), the catheter obviously has a liquid carrying tube.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alyssa M Alter
Examiner
Art Unit 3762



JEFFREY R. JASTRZAB
PRIMARY EXAMINER
10/25/05